510(k) Summary

510(k) SPONSOR: Vivorté, Inc.
1044 E. Chestnut Street
Louisville, KY 40204
Contact: Robert Burden
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Telephone: (502) 693 - 2432
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AUG 12 2013

TRADE NAME: Vivorté BVF™ Lite™

COMMON NAME: Calcium phosphate bone void filler; bone void filler

Product	Regulation and Description	Product Code	Device	Device Class
Vivorté BVF™ Lite™	21 CFR 888.3045 - Resorbable calcium salt bone void filler device	MQV	Filler, bone void, calcium compound	II

PREDICATE DEVICES: Synthes® Norian® SRS® Bone Void Filler (K011897)

DEVICE DESCRIPTION:

Vivorté BVF™ Lite™ is a moldable, self-setting, gradually resorbable, biocompatible, calcium phosphate bone void filler. Vivorté BVF™ Lite™ is indicated for use to fill bony voids or defects of the skeletal system (i.e., extremities, pelvis) that may be surgically created or osseous defects created from traumatic injury to the bone and only for bony voids or defects that are not intrinsic to the stability of the bony structure. Vivorté BVF™ Lite™ may be manually applied to the bony defect or applied to the defect through a cannula. Vivorté BVF™ Lite™ isothermally hardens *in vivo* to form a carbonated apatite (hydroxyapatite). Vivorté BVF™ Lite™ has a compressive and bending strength that is greater than that of human cancellous bone. The carbonated apatite (hydroxyapatite), which closely resembles the mineral phase of bone, provides an osteoconductive scaffold for bone healing. The device is gradually resorbed and remodeled by the body as new bone formation occurs during the healing process. Vivorté BVF™ Lite™ is provided in various kit sizes corresponding to the amount of bone void filler produced when the components of the kit are mixed together.

INTENDED USE AND INDICATIONS FOR USE:

Vivorté BVF™ Lite™ is a moldable, self-setting, gradually resorbable, calcium phosphate bone void filler. Vivorté BVF™ Lite™ is indicated for use to fill bony voids or defects of the skeletal system (i.e., extremities, pelvis) that may be surgically created or osseous defects created from traumatic injury to the bone and only for bony voids or defects that are not intrinsic to the stability of the bony structure. Vivorté BVF™ Lite™ may be manually applied to the bony

defect or applied to the defect through a cannula. Vivorté BVF™ Lite™ is gradually resorbed and remodeled by the body as new bone formation occurs during the healing process.

BASIS FOR SUBSTANTIAL EQUIVALENCE:

Vivorté BVF™ Lite™ is chemically and physically substantially equivalent to the Synthes® Norian® SRS® Bone Void Filler. Both the Vivorté BVF™ Lite™ and the Synthes® Norian® SRS® Bone Void Filler are composed of synthetic calcium phosphate materials that are virtually identical. Both the Vivorté BVF™ Lite™ and the Synthes® Norian® SRS® Bone Void Filler devices are intraoperatively prepared by mixing similar components together to produce self-hardening calcium phosphate bone void fillers that, when implanted in a bony defect, are resorbed and remodeled by the body as new bone formation occurs during the healing process. Both devices have comparable mixing, handling/working, and setting times; and both of these devices, when fully hardened, are composed primarily of hydroxyapatite that have similar chemical, physical, and mechanical characteristics and properties. The indications for use of the Vivorté BVF™ Lite™ and the Synthes® Norian® SRS® Bone Void Filler are similar.

The Vivorté BVF™ Lite™ and Synthes® predicate device are provided packaged sterile and are intended as prescription use only single use devices.

Non-Clinical Testing

The following testing was performed to demonstrate substantial equivalency of Vivorté BVF™ Lite™ to the predicate devices.

- Chemical, physical and mechanical testing
- Biocompatibility and toxicity (ISO 10993; ASTM; USP) for permanent implants
- Animal testing

Clinical Testing

Clinical testing was not necessary to determine substantial equivalence between Vivorté BVF™ Lite™ and the predicate device.

CONCLUSIONS

The nonclinical tests (i.e. chemical, physical, mechanical, biocompatibility, and animal tests) conducted demonstrate that Vivorté BVF™ Lite™ device is substantially equivalent to the cited predicate device and that the Vivorté BVF™ Lite™ device is therefore as safe, as effective, and performs as well as or better than the predicate device. No clinical tests were conducted or submitted in support of substantial equivalency.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 12, 2013

Vivorté, Incorporated
% Peoples & Associates
Mr. Stephen J. Peoples
5010 Lodge Pole Lane
Fort Wayne, Indiana 46814

Re: K131133
Trade/Device Name: Vivorté BVF™ Lite™
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: June 26, 2013
Received: July 1, 2013

Dear Mr. Peoples:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K131133

Device Name: Vivorté BVF™ Lite™

Indications for Use:

Vivorté BVF™ Lite™ is a moldable, self-setting, gradually resorbable, calcium phosphate bone void filler. Vivorté BVF™ Lite™ is indicated for use to fill bony voids or defects of the skeletal system (i.e., extremities, pelvis) that may be surgically created or osseous defects created from traumatic injury to the bone and only for bony voids or defects that are not intrinsic to the stability of the bony structure. Vivorté BVF™ Lite™ may be manually applied to the bony defect or applied to the defect through a cannula. Vivorté BVF™ Lite™ is gradually resorbed and remodeled by the body as new bone formation occurs during the healing process.

Prescription Use __X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K131133